
**Health informatics — Identification
of medicinal products — Data
elements and structures for the
unique identification and exchange of
regulated information on substances**

*Informatique de santé — Identification des produits médicaux —
Éléments de données et structures pour l'identification unique et
l'échange d'informations réglementées sur les substances*

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2. www.iso.org/directives

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received. www.iso.org/patents

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: Foreword - Supplementary information.

This document was prepared by ISO/TC 215, *Health informatics*.

This second edition cancels and replaces the first edition ISO 11238:2012^[2], which has been technically revised.

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Introduction

This document was developed in response to a worldwide demand for internationally harmonized specifications for medicinal products. It is one of a group of five standards and four technical specifications which together provide the basis for the unique identification of medicinal products. The group of standards and technical specifications comprises:

ISO 11615[3], *Health informatics — Identification of medicinal products — Data elements and structures for the unique identification and exchange of regulated medicinal product information*

ISO 11616[4], *Health informatics — Identification of medicinal products — Data elements and structures for the unique identification and exchange of regulated pharmaceutical product information*

ISO 11238, *Health informatics — Identification of medicinal products — Data elements and structures for the unique identification and exchange of regulated information on substances*

ISO 11239[5], *Health informatics — Identification of medicinal products — Data elements and structures for the unique identification and exchange of regulated information on pharmaceutical dose forms, units of presentation, routes of administration and packaging*

ISO 11240[6], *Health informatics — Identification of medicinal products — Data elements and structures for the unique identification and exchange of units of measurement*

ISO/TS 19844, *Health informatics — Identification of medicinal products — Implementation guidelines for data elements and structures for the unique identification and exchange of regulated information on substances*

ISO/TS 20440[7], *Health informatics — Identification of Medicinal Products — Implementation guide for ISO 11239 data elements and structures for the unique identification and exchange of regulated information on pharmaceutical dose forms, units of presentation, routes of administration and packaging*

ISO/TS 20443[8], *Health informatics — Identification of Medicinal Products — Implementation guide for ISO 11615 data elements and structures for the unique identification and exchange of regulated Medicinal Product information*

ISO/TS 20451[9], *Health informatics — Identification of Medicinal Products — Implementation guide for ISO 11616 data elements and structures for the unique identification and exchange of regulated pharmaceutical product information*

These standards for the identification of medicinal products (IDMP) support the activities of medicines regulatory agencies worldwide by jurisdiction. These include a variety of regulatory activities related to development, registration and life cycle management of medicinal products, as well as pharmacovigilance and risk management.

To meet the primary objectives of the regulation of medicines and pharmacovigilance, it is necessary to reliably exchange medicinal product information in a robust and reliable manner. The IDMP standards therefore support the following interactions:

- between one medicine regulatory agency and another, e.g. European Medicines Agency to the US Food and Drug Administration (FDA), or vice versa; and between the European Medicines Agency and the National Competent Authorities in the EU, vice versa;
- between pharmaceutical companies and medicine regulatory agencies, e.g. "Pharma Company A" to Health Canada;
- between the sponsor of a clinical trial to a medicine regulatory agency, e.g. "University X" to the Austrian Agency for Health and Food Safety (AGES);
- between a medicine regulatory agency and other stakeholders, e.g. UK Medicines and Health Care Products Regulatory Agency (MHRA) to the National Health Service (NHS);

- between medicine regulatory agencies and worldwide-maintained data sources, e.g. the Pharmaceutical and Medical Device Agency (PMDA) and the organization responsible for assigning substance identifiers.

Unique identifiers produced in conformance with the IDMP standards will support applications for which it is necessary to reliably identify and trace the use of medicinal products and the ingredients within medicinal products.

This document provides a structure that enables the assignment and maintenance of unique identifiers for all substances in medicinal products. This document sets out the general rules for defining and distinguishing substances, and provides a high-level model for substances and specified substances to support the organization and capturing of data.

It is anticipated that implementation will use the ISO/TS 19844 and HL7 messaging (see 5.8) to deliver a strong, non-semantic unique identifier for every substance present in a medicinal product. It is anticipated that a single maintenance organization will be responsible for the generation of global identifiers for every substance and that such an organization would retain the defining elements upon which the substance identifier was based. At the specified substance level, a more regional approach may be necessary because of the proprietary nature of much of the information.

The use of the identifier is essential for the description of substances in medicinal products on a global scale. This document does not involve developing nomenclature for substances or specified substances, but common and official substance names in current use can be mapped to each identifier.

Ingredients used in medicinal products range from simple chemicals to gene-modified cells to animal tissues. To unambiguously define these substances is particularly challenging. This document defines substances based on their scientific identity (i.e. what they are) rather than on their use or method of production. Molecular structure or other immutable properties, such as taxonomic, anatomical and/or fractionation information, are used to define substances. This document contains five single substance types and a mixture substance class that are sufficient to define all substances. Although it is certainly possible to define or classify substances in other ways, this document uses a minimalistic structured scientific concept approach focusing on the critical elements necessary to distinguish two substances from one another. There are frequently interactions between substances when they are mixed together, but this document has intentionally not included these supramolecular interactions at the substance level because of the variable nature and strength of such interactions. This document also allows for the capture of multiple terms which refer to a given substance and a variety of reference information that could be used to classify substances or relate one substance to another.

In addition to the substance level, this document also provides elements for the capture of further information on substances that make up the defining characteristics of specified substances, such as grade, manufacturer, manufacturing information and specifications, and also to capture information on substances that are frequently combined together in commerce but are not strictly a medicinal product. At the specified substance level, four groups of elements provide information essential to the tracking and description of substances in medicinal products.

The basic concepts in the regulatory and pharmaceutical standards development domain use a wide variety of terms in various contexts. The information models presented in this document depict elements and the relationship between elements that are necessary to define substances. The terms and definitions described in this document are to be applied for the concepts that are required to uniquely identify, characterize and exchange information on substances in regulated medicinal products.

The terms and definitions adopted in this document are intended to facilitate the interpretation and application of legal and regulatory requirements, but they are without prejudice to any legally binding document. In case of doubt or potential conflict, the terms and definitions contained in legally binding documents prevail.

In this document, “% (V/V)” is used in place of “% volume fraction”.